

APPLICANT(S): KEREN, Gad et al.
SERIAL NO.: 09/839,643
FILED: April 20, 2001
Page 2

AMENDMENTS TO THE SPECIFICATION

Please replace paragraph 25 with the following rewritten paragraph:

-- [0025] Referring now to FIG. 2, another aspect of the devices of the present invention is that the shunt 100 may or may not be in fluid communication with a pump 140, such as either a surgically implanted pump that continuously moves a small amount of blood from one chamber or area to another, for example from the left ventricle chamber to the aorta for chronic reduction of LVEDP. Alternatively, the invention can include a catheter-based pump that continuously moves a small amount of blood from the LV chamber to the aorta for acute reduction of LVEDP. In certain preferred embodiments, the pump and valve will have a heart-synchronized actuated valve to allow specific regimens of left-to-right shunting to be applied. As seen in FIG. 2, after the shunt 100 is placed in a septum 135 or other area, the pump 140 may be placed so as to direct fluid toward the shunt, the pump may be directly connected to the shunt, juxtaposed to the shunt, or displaced from the shunt but capable of directing flow in such a way as to effect more efficient pressure reduction. --

Please replace paragraph 26 with the following rewritten paragraph:

-- [0026] FIG. 2 shows an implant similar to that of FIG. 1 that is placed surgically for the chronic reduction of LVEDP. This device includes a relatively small-sized pump 140, which can be similar to those used in Left-Ventricular Assist Devices (LVADs). Unlike the LVAD, however, the disclosed invention does not seek to significantly "support" the function of the left ventricle by pumping blood from the LV chamber to the body. Rather, it is intended only to "offload" the excessive pressure that builds through the diastolic phase of the cardiac cycle in some CBF patients. Whereas a normal LVEDP is in the range of 6-12 mmHg, patients with diastolic dysfunction heart failure (DDHF), end-diastolic pressure (EDP) in the left atrium (LA) and left ventricle (LV) can rise considerably above normal levels. Therefore the present invention encompasses a number of embodiments that are both capable of being either implanted during a surgical procedure or using a catheter (percutaneous). The shunt 100 allows blood to flow in the direction shown by the arrows so long as there is a lower pressure in the chamber or vessel adjoining the LV. In any embodiment, the methods and apparatus of the present invention reduce EDP, and in

APPLICANT(S): KEREN, Gad et al.
SERIAL NO.: 09/839,643
FILED: April 20, 2001
Page 3

particular mitigate the most severe consequences of significantly increased EDP, such as pulmonary edema. --

Please replace paragraph 28 with the following rewritten paragraph:

-- [0028] As explained above, although one class of embodiments of the present invention is designed to be purely mechanical and will have certain advantages, the present invention also encompasses additional embodiments wherein additional features such as internal signal processing unit 148 and an energy source 150, such as a battery, are included. In such embodiments, the shunts described above will include a valve apparatus that responds to conditions other than those occurring within the heart and/or has internal signal processing requiring an energy source. A device of this type responds according to programmed algorithms to all of the conditions mentioned above. The signal processing ability of devices in such embodiments enable adaptive approaches as well, in which the device response to conditions will change over time according to a pre-programmed adaptation algorithm. Such embodiments will include additional apparatus, such as a power source 150, sensors 155 and the like. The provision of implantable, programmable electrical devices that collect cardiac data and effect the operation of certain other elements of a device are well known in the field of cardiac pacing, for one example. In one particular embodiment, the actively controlled valve of the shunt as in senses and responds to electrical signals so as to act in synchronization with the cardiac cycle. --

Please replace paragraph 29 with the following rewritten paragraph:

-- [0029] Either passive or active devices may be linked to an external indicator 157, such as pendant worn by the patient, that displays the device status. Such an indicator enables the patient to notify a physician in the event of an activation of the implanted device that corresponds to the significantly exacerbated state heart failure. In this case, the device will be acting to prevent the occurrence of pulmonary edema during the time that the patient notifies a physician and then undergoes medical treatment to reduce the severity of the patient's condition. --

Please replace paragraph 39 with the following rewritten paragraph:

APPLICANT(S): KEREN, Gad et al.
SERIAL NO.: 09/839,643
FILED: April 20, 2001
Page 4

-- [0039] Although the present invention provides new and useful methods of treatment, the techniques of implanting shunts as described herein is well known. For one example, in a preferred embodiment of the present invention, as illustrated in FIGS. 3-5, a transseptal needle set 160 is advanced toward the wall of the right atrial septum. Access has been made from the femoral vein with the system being advanced through the inferior vena cava and into the right atrium. Devices that allow such access and subsequent transseptal puncture are available from Cook Incorporated. For example, the procedure can be carried out using a stainless steel and obturator set TSNC-18-71.0 for adults and TSNC-19-56.0 for pediatric patients. Once transseptal puncture has been achieved, a guidewire 170 is exchanged for the needle component in the commercially available device described above and then passed into the left atrium. The process of securing catheter access to the left atrium by way of a transseptal puncture is further described in the standard medical text Braunwald, Heart Disease, (Ch. 6, p. 186) which is incorporated herein by reference. After the transseptal sheath 165 is positioned in the left atrium, as describe above, the placement of a shunt 100 made in accordance with the present invention is initiated. The following is a generalized sequence; the placement procedure will be done according to the typical methods of interventional cardiology as are well known to physicians trained in that subspecialty. The typical supporting apparatus found in the cardiac catheterization laboratory will be used, such as fluoroscopy for visualization and hemodynamic and ECG monitoring equipment to assess catheter position and patient vital signs. --